TABLE B2			
Individual Animal Tumor Pathology	of Female Rats in the	e Lifetime Inhalation Stud	y of Talc: 0 mg/m ³ (continued)

Number of Days on Study	7 8 6	7 8 9	8 0 0	8 0 5	8 0 8	8 1 3	8 1 6	8 1 7	8 2 4	8 2 7	8 3 5	8 4 1	8 4 6	8 5 9	8 6 2	8 6 2	8 6 2	8 6 2	8 6 2	8 6 3	-	8 6 3	8 6 3	8 6 3	8 6 3	
Carcass ID Number	4 2 5 1	3 1 1 1	3 5 5	3 3 6 1	3 0 1 1	4 2 4 1	3 7 3 1	4 2 7 1	3 8 3 1	3 5 2 1	3 7 4 1	3 5 6 1	4 0 3 1	4 2 2 1	3 0 3 1	3 1 2 1	3 2 9 1	3 3 0 1	3 3 2 1	3 8 0 1	3 8 1	3 9 9	4 0 0	4 0 7 1	4 2 8 1	Total Tissues Tumors
Respiratory System Larym Adenocarcinoma, metastatic, thyroid	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
giand Lung Adenocarcinoma, metastatic, multiple,	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	1 50
mammary gland Alveolar/bronchiolar adenoma Nose Trachea	+ +	++	++	X + +	++	++	++	++	++	++	++	++	++	++	++	++	++	++	++	++	++	++	++	++	++	1 1 48 50
Special Senses System Eye Harderian gland	•								+	+					_		+				=		<u>-</u>			2 5
Urinary System Kidney Urinary bladder	+	++	++	+	+	++	++	+,	.+	++	++	+	+	+	++	++	++	+	+	++	+	+	++	++	++	49 50
Systemic Lesions Multiple organs Leukemia mononuclear	*	+	+	+	+	+	+	+	+	+ X	+ X	+ X	+	+ X	+	+	+	+	+	+	+	+	+ ×	+	+	50 13

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B-12 Talc, NTP TR 421

														_	_	_	_	_	_	_	_	_	_	_	_
number of Days on Study	4 8 2	5 0 8	5 2 6	5 5 7	5 6 1	5 6 6	5 6 6	6 4 7	6 5 1	6 6 8	7	6 9 0	-	7 0 5	2	7 2 4	7 2 9	7 3 8	4	7 4 7	5			6	
		_	0	1	0	_	0	1	0	1	1	0	0	0	_	1	1	0	1	0	1	0	0	0	0
Carcass ID Number	3	4	6	3	6	4	9	1	9	4	1	4	9	7	4	0	6	8 9 1	1 5 1	9	2	7	3	1 7 1	3
limentary System			-					_																	
Esophagus	+	A	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Intestine large	+	Α	+	+	+	+	+	٨	+	+	+	+			Α				+	+	+	Α	+	A	+
Intestine large, cocum	+	Α	+	+	+	+	+	A	A	+			A												
Intestine large, colon	+	Α	+	+	+	+	+	Α	+	+	+	+	+	+	Α	+	A	+	+	Α	+	Α	+	Α	+
Intestine large, rectum	+	Α	+	+	+	+	+	Α	M	+	M	M	M	+	М	+	A	+	+	+	+	M	+	Α	+
Intestine small	+	A	+	+	+	+	+	Α	Α	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Intestine small, duodenum	+	Α	+	+	+	+	+	Α	Α	+	+	+	+	+	+	+	Α	+	+	+	+	+	+	+	+
Intestine small, ileum	+	Α	Α	+	+	+	+	Α	Α	+	Α	+	Α	+	Α	Α	Α	+	+	Α	+	Α	+	Α	+
Intestine small, jejunum	+	A	+	+	+	+	+	Α	Α	+	+	+	+	+	Α	+	Α	+	+	Α	+	Α	+	Α	+
Liver Hepatocellular carcinoma	+	A	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Neoplastic nodule																X									
Mesentery				•												_							+		+
Pancreas .	+	A	+	+	+	+	+	A	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Salivary glands Lymphoma malignant lymphocytic, metastatic	+	A	+	+	+	+	+	.+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Sarcoma					Х																				
Stomach	+	A	+	+	+	+	+	+	+	+	+	+	+	+	+	+	A	+	+	+	+	+	+	+	+
Stomach, forestomach Stomach, glandular	+	A	+	+	+	+	+	+	+	+	+	+	+	+	+	+	A	+	+	+	+	+	+	+	+
Tongue	'	^	•	,	+	Ċ	•	•	Ċ	•	•	•	•	,	•		•	•	•	•	•	•	•	•	•
Sarcoma, metastatic					X																				
Squamous cell papilloma																									
Tooth											+														
Adamantinoma benign											Х														
ardiovascular System																									
Blood vessel															+										
Heart	+	A	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ndocrine System																									
Adrenal gland	+	Α	+	+	+	+	+	Α	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Adrenal gland, cortex	+	Α	+	+	+	+	+	Α	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Adrenal gland, medulia	+	Α	+	+	+	+	+	Α	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Pheochromocytoma malignant Pheochromocytoma benign														x						x			x		
Bilateral, pheochromocytoma benign																						х			
Islets, pancreatic Adenoma	+	A	+	+	+	+	+	A	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	M
Parathyroid gland			_	_		_	14	_	_	_	14	4	+	_		_	_	_	_	_	۰	T		. 4	_,
	7	~	7	7	٠	7							+								7				
Pituitary gland	*	A	+	~	_	7	+		+	+	_	~	X		~	_			X	+	Ţ	+	+	+	
Pars distalis, adenoma						v						x		^				^	^	^	^				X
Pars distalis, carcinoma Thyroid gland				J.		۸		_					+		_	_	_	_			ی ۔		د.		
	~	\sim	7	~	~	7	~	~	~	~	~	~	~	•	~	~	~	7	~	u	_	~	~	+	_
C-cell, carcinoma		•																							

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TABLE B2
Individual Animal Tumor Pathology of Female Rats in the Lifetime Inhalation Study of Talc: 6 mg/m³ (continued)

Individual Animal Tumor Patholog					_				_										_		_	_		_	·
	7	7	7	7	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8	
Number of Days on Study	8	9	9	9	0	_		1		-	4	6		6		6	6	6	6	6	6	6	-	6	
	6	8	8	9		2				1				2	2	2	2	2	3	3	3	3	3	3	
	1	0	1	1	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	1	1	1	1	
Carcass ID Number	4	2	4		8	1	3		1	4	6	1	1	2	2	4	6	7	8	9	1	3	3	4	Total
	4	4	3	8		4	7		7		4	6			1							3	6	0	Tissues
	1	1	1	1	1	1	1		1	1	1	1			1			1					1	1	Tumors
Alimentary System																		_		_					
Esophagus	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	48
Intestine large	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	43
Intestine large, cecum	Α	A	A	A	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	34
Intestine large, colon	+	A	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	41
Intestine large, rectum	+	M	+	+	+	+	+	+	+	М	+	+	+	+	+	+	+	+	+	+	+	+	+	+	37
Intestine small	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	46
Intestine small, duodenum	+	+	+	+	+	+	+	+	M	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	44
Intestine small, ileum	A	. Α	-		+	Α	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	32
Intestine small, jejunum	+	Α			+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	40
Liver	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	•	48
Hepatocellular carcinoma					•								٠											X	1
Neoplastic nodule Mesentery					X				X																3
Mesentery Pancreas						.1	J.	,	j.	. 1	,	_,		_1					٠						2
Salivary glands	+	M	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	٠,	+	+	*	+	+	"	46 48
Lymphoma malignant lymphocytic, metastatic	-	x	_	_	_	_	_	_	_	_	*	_	_	٦	+	+	+	+	+	+	+	+	+	+	
Sarcoma		^																							1
Stomach	_				_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	1 47
Stomach, forestomach						T	_	Ι	Ι		Ι	Ι		Ţ	T.	+	T.	I	Ξ	T	Ι	Ţ	I	Τ.	45
Stomach, glandular	_ T			_ <u>_</u>	I	T	I	T	_	I	Ι	T	_	_	M	T	M	Ι	_	Ι	Ι	Ξ	Ι	Ξ	47
Tongue	7	-	•	+	•	Τ.	_	т	-	т	•	_	Τ.	т	т	•	_	т	т	•	7	т	Τ	т	2
Sarcoma, metastatic				•																					ĩ
Squamous cell papilloma				Х																					i
Tooth Adamantinoma benign																									i 1
Cardiovascular System																					_				
Blood vessel					_														_						3
Неап	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	48
Endocrine System										•															
Adrenal gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	47
Adrenal gland, cortex	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	47
Adrenal gland, medulla	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	47
Pheochromocytoma malignant									_		X	_													1
Pheochromocytoma benign						X			X		X	Х				Х			X	X					10
Bilateral, pheochromocytoma benign	X				X																			X	4
Islets, pancreatic	+	М	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	45
Adenoma		٠.		, .													_							X	1
Parathyroid gland	+	M	M	ı Į	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	42
Pituitary gland	+	+	+	+	*	+	+	+	+ v	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	47
Pars distalis, adenoma Pars distalis, carcinoma	Х		λ	X	^	٨	٨		Х		X		v	X								X	X		18
· · · · · · · · · · · · · · · · · · ·	د	_	.1	.1			٠.	ı		ر	J.	ı	X	ı	,	ı	,		,	,	,				3
Thyroid gland	+	+	+	+	+	+	+	Y	+	X	+	+	+	+	+	+	+	+	+	+	+	+	+	+	47
C-cell, carcinoma					x			X		^															2
Follicular cell, adenoma					^																				1

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B-14 Taic, NTP TR 421

								_				_													
Number of Days on Study	8	5 0 8	2	5	6	5 6 6	6	4	5	6	7	9		0	7 2 0	2	7 2 9	3	4	4	5	7 6 0	6	7 6 6	6
Carcass ID Number	0 3 8 1	8	0 6 8 1	1 3 7 1	6	0 4 3 1	9 5	1 1 0 1	-	4	1 8	4 5	0 9 2 1	0 7 0 1	0 4 0 1	0	1 1 6 1	8	1 1 5 1	3	1 2	6	2	7	6
eneral Body System None																									
enital System																_									
Clitoral gland	+	A	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	M	M	+	+	+	M	M
Ovary Granulosa cell tumor benign	+	A	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Granulosa cell tumor benign Granulosa-theca tumor benign																		x							
Uterus	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Lymphoma malignant lymphocytic,	•	•	•	•	•	٠	٠	•	•	•	•	•	•		•	•	•	•	•	•	•	•	т.	•	•
metastatic																				•					
Polyp stromal											X				X									X	
Sarcoma stromal				X																					
ematopoietic System								_										_			·				
Bone marrow	+	Α	+	+	+	+	Α	Α	+	+	+	+	Α	+	+	+	+	+	+	+	+	A	+	+	+
Lymph node	+	A	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Lymph node, bronchial	+	Α	+	+	+	+		+	+	+	+	+	+	+	M	+	+	+	+	+	+	+	+	+	+
Lymph node, mandibular	+	A	+	M		+	+	A	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Sarcoma, metastatic Lymph node, mediastinal					X																				
Lymph node, mesenteric	+	A			++	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	M	+	+
Spleen	+	A	+					A +	+	•	-	•	•	•	+	+	+	+	+	+	+	+	+	+	+
Thymus		^	+	⊤		,	+		+		+				+		+	•	+	+	+	+	+	+	+
Mixed tumor malignant	•	•	•	•	•	,	4.		X	τ.	7	141	141	~	~	т	~	•	~	Т	т	~	+	+	T
Мухота															X										
																_									
tegumentary System																									
Mammary gland	+	+	+	+	+	+	+	+	+	+	M	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Adenoma																									
Fibroadeno <u>ma</u> Fibroma	X				Х																X	X		X	
Lymphoma malignant lymphocytic,																									
metastatic																									
Skin	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Keratoacanthoma Subcutaneous tissue, fibrosarcoma																			x						
PROCEEDINGS INSUC, HUICEATCUES .																			x						

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TABLE B2					
Individual Animal Tumor	Pathology of F	Female Rats in th	e Lifetime Inha	lation Study of Tale	: 6 mg/m³ (continued)

Individual Animal Tumor Pathology	of Fen	aal	e I	₹at	s i	n t	he	Li	fet	im	e 1	nh:	ala	tio	n :	Stı	ıdy	0	T	alc	: 6	n	ıg/ı	n³ (c	ontinued)
	7	7	7	7	8	8	8	8	8	8	g	8	8	8	8	8	8	8	8	8	8	8	8	8	
Number of Days on Study	8	9	9	9	0	1		1			4		6	6	6	6	6	6	6	6	6	6	6	6	
	6	8	8	9	0	-				1			2		2	2	2	2					3		
													_												···
Co TD M	1	0	1	1						0			0	0		0	0	0			_	-	1 3	-	Total
Carcass ID Number	4	2	4	3	8	1	3	6	1	4	6	1	1	2	2	4	6	7	8	9	1		-		
	4	4	3	8	5		7		7		4			0					6						Tissues
	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	Tumors
General Body System None																									
Genital System																									
Clitoral gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	44
Ovary	· .	+	+		+	+	+	+	+	+	+	<u>.</u>	÷	+	+	+	+	+	+	+	+	+	м	+	47
Granulosa cell tumor benign	•	•	•	•	•	•	•	·		•	•	•	•	•	•	٠	•	•	•	x	X	•		•	2
Granulosa-theca tumor benign																				-	•				ī
Uterus		+	4	+	+	4	4	+	_	4	+	_	_	4	_	4	_	_		4	_	4	М		48
Lymphoma malignant lymphocytic,	•	•	7	•	•	•	•	•	7	•	•	_	•	_	_	•	•	_	7	7	_	7	141	•	•••
metastatic		х																							1
Polyp stromal		^							x				х			x		х							7
Sarcoma stromal									^				^			^		^							í
Hematopoietic System					_	_			_													-	_		
Bone marrow	_	_	٨	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	٠.	_	43
Lymph node		ì			_	1	I	1	1	1	Ι	1	I	1	<u> </u>				I					Ĭ.	48
Lymph node, bronchial		_			Ι		T	Ι		—	I	T	+	_	+		T	T	Ŧ	I		T		+	47
Lymph node, mandibular						I		Τ			Ξ	T	T	T		Ι	T	T	T	T	Τ	Ξ		Ι	46
Sarcoma, metastatic	•	•	•	7	-	•	7	•	•	_	7	т	т	т	т	т	т	т	т	Τ	_	т	т	т	1
Lymph node, mediastinal	_	_	_	_	_	_	_	_	14	м	_		_	_	_	_		_	_		_	_		_	44
Lymph node, mesenteric		Ι	I		T	Ŧ	Ι		IVI	IVI	Ι	Τ	+	+	+	Ι	IAI	_	Ι	T	-	Ι	+	+	47
Spleen		_ <u>_</u>	Ŧ		Ι			I	T		Ι	I	+	I			T	+	+	+		I	•	+	47 48
Thymus				_	T.		_		Ι	_	_	<u> </u>	Ξ	T	_	Ι	Ι	Ι	Ι		+		+	Ξ	46 44
Mixed tumor malignant	т		Τ	_	т.	т	т	т	т	т	•	т	_	т	_	т	т	_	_	IAI	_	_	_	_	1
Myxoma																									i
Intro			_			_														_	_		_		
Integumentary System																									
Mammary gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	48
Adenoma			.,								37			٠,								X		X	2
Fibroadenoma			X								X			X	X								X		10
Fibroma													X												1
Lymphoma malignant lymphocytic,																									_
metastatic		X																							1
Skin	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		+	49
Keratoacanthoma																						Х			1
Subcutaneous tissue, fibrosarcoma																									1

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B-16 Talc, NTP TR 421

Number of Days on Study	8	0	2	5 5 7	6	6	6	4	5	6	7	9	9	0	2	2	2	3	4	4	5	7 6 0	6	6	6	
Carcass ID Number		0 4 8		1 3 7	0 6	0 4 3	0 9	1 1	_	1 4	1 1	0 4	0 9	0 7	0	1 0	1 1	0	1 1	0	1 1			•		
	-		_	i			_	-										-	-		_					•
Musculoskeletal System Bone Mandible, sarcoma, metastatic Skeletal muscle Liposarcoma	+	A	+	+	* X	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
Nervous System Brain Carcinoma, metastatic, pituitary gland	+	A	+	+	+	+ X	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
Respiratory System Larynx Lung Nose Trachea	+ + + +	A A A		++++	+ + + +	++++	+ + + +	+ + A +	+ + + +	++++	++++	+ + + +	+ + + +	++++	+ + + +	+ + + +	+ + A +	++++	+ + + +	+ + + +	+ + A +	+ + + +	++++	+ + + +	+ + + +	
Special Senses System Harderian gland										+													+			
Urinary System Kidney Lipoma Lymphoma malignant lymphocytic, metastatic	+	A	+	+	+	+	+	Α	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
Urinary bladder	+	A	+	M	+	+	+	A	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
Systemic Lesions Multiple organs Leukemia mononuclear Lymphoma malignant lymphocytic Lymphoma malignant mixed	+	+	*	+	+	+	*	* X	+	* X	+		+ X	+	+	+ x	*	+ X	+	+ x x	+	*	+	+ x	+	

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TABLE B2		
Individual Animal Tumor Pathology	of Female Rats in the Lifetime	e Inhalation Study of Talc: 6 mg/m ³ (continued)

Individual Ammai Tumor Tathology	or r-cu	uai		\u_L			110	14	101	щ		****	aıu		***		u	U			- •		φ,		(Willian	101)
	7	7	7	7			8																			
Number of Days on Study	8 6	9 8	9 8	9	0	1 2		1 8		1	9	6 2	6 2		6	6 2		6 2					6 3			
	1	0	1	1	0	0	0				0	0	0	0	0	0	0	0	0	0	1	1	1	1		
Carcass ID Number	4	2	4	3	8	1	3	6	1	4	6	1	1	2	2	4	6	7	8	9	1	3	3	4		Total
	4	4	3	8			7				4	6	8		1											Tissues/
	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1		Tumors
Musculoskeletal System																										
Bone	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		48
Mandible, sarcoma, metastatic																										1
Skeletal muscle Liposarcoma						•																+ X				1
·						_																_				•
Nervous System																										
Brain Carcinoma, metastatic, pituitary gland	+	+	+	+	+	+	+	+	-	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		48 1
Respiratory System						_																				
Larynx	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	•	48
Lung	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		48
Nose	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		45 .
Trachea	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		48
Special Senses System																										
Harderian gland			+					+							+			+					+			7
Urinary System																										
Kidney	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		47
Lipoma																						X				1
Lymphoma malignant lymphocytic,																										
metastatic Urinary bladder	.1	X	ı		_	_	_	_	_	_	_	_				_	_			_	,		м			1 45
		_	_	_	_	_	_	_	_	_	_	_	*	-	_	_	_	+	+	_	_	_	IV.	_		43
Systemic Lesions																										
Multiple organs	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		49
Leukemia mononuclear Lymphoma malignant lymphocytic		х	Х											Х	X	Х				X	Х	Х	X	X		20 2
		^																								
Lymphoma malignant mixed																										1

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B-18 Taic, NTP TR 421

TABLE B2				_
Individual Animal Tumor	Pathology of Female	Rats in the Lifetime	Inhalation Study of Talc:	18 mg/m³

	5	5	<	5	6	6	6	6	6	6	6	6	6	6	6	7	7	7	7	7	7	7	7	7	7	
Number of Days on Study	3	5	8	9	1	3	4	6	6	7	7	7	8	9	9	Ó	í	1	1	2	3	4	4	4	7	
Number of Days on Stady	6	_	6	4			6											-					6	7	3	
	1	2	2	2	1	2	2	2	1		2	2	2	2	1	2	1	2	2		1	_	-	2	-	
Carcass ID Number	6	8	1	1	8	8		8		-	0			4	8	0			3					3		
	7	0	6	2		5	0	1					8 1											9		
			_						_																	
Mimentary System		_		_	_	_	_	_		_	_	_	_	_	_	_	_	_	_	_	_		_		_	
Esophagus Intestine large	I		7		I	_	I	T	T		I	Ĭ	Ι	T	T	<u> </u>	1	Ι	1	1	i	Ĭ	ì		ì	
	I		A	+	I	Â	+	+	+	I	M	+	I	_	<u> </u>	+	I	I	Ι				Ā		1	
Intestine large, cecum								+	+		141	Ξ	T	_	<u> </u>		1	T	1	<u> </u>	_	Α.			ì	
Intestine large, colon	+	T M	A		+ +			+	+		+	T	M	<i>∓</i>	4	4	-	+		м	<u> </u>	<u> </u>	→	. <u>↓</u>	∓	
Intestine large, rectum Intestine small	+	M	A.	T.	. T	Α.	+	+	+		+	T	141	+	+	+	T	+	+	T.	. . ⊥		T	_ _	∓	
Intestine small Intestine small, duodenum	+	+	٨	+	+	+	. .		+	-	<u> </u>	→	_	<u> </u>	∓	+	_	T	M	-	-	→	-	→	→	
Intestine small, duodenum Intestine small, ileum	T 	T	A		+	*	Ā				→		A	⊤	A		<u> </u>	_			•	→	A	. +		
Intestine small, jejunum	+	+	, ,	T	∓		+					+	+	+	+	+	→	T	+	→	^	∓		· +		
Liver	+	∀	+	T	+		+				+	+		+			+	+		+	7		<u> </u>		_	
Granulosa-theca tumor malignant, metastatic, ovary	•	_	_	Т	7	•	•	т	_	Т	7	_	•	_	T	x	•	_	•	т	7	_	•	•	•	
Neoplastic nodule																										
Pancreas	+	+	A		+	+	+	+	+	+	+	+	+	+	+	+	+	+.	+	+	+	+	+	+	+	
Pharynx				+																						
Squamous cell carcinoma				X																						
Salivary glands	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
Fibrosarcoma																										
Stomach	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
Stomach, forestomach	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
Stomach, glandular	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
Cardiovascular System																										
Blood vessel																										
Heart	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
Granulosa-theca tumor malignant,																										
metastatic, ovary																X										
Endocrine System					_																					
Adrenal gland	+	+	Α	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
Adrenal gland, cortex	+	+	Α	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
Granulosa-theca tumor malignant, metastatic, ovary																x										
Adrenal giand, medulia	+	+	Α	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
Granulosa-theca tumor malignant, metastatic, ovary																X										
Pheochromocytoma malignant																										
Pheochromocytoma benign																							х			
Bilateral, pheochromocytoma malignant																							^			
Bilateral, pheochromocytoma benign															x		x									
Islets, pancreatic	+	+	A	+	+	+	+	+	+	+	+	+	+	+	+	+	+	4	+	+	+	+	+	+	+	
Adenoma	,	•	•••	•	•	•	x	•	٠	•	•	•	٠	•	•	•	•	,		•	•	•	•	•	,	
							~~																			

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TABLE B2						•					
Individual Animal	Tumor	Pathology	of Female	Rats	in the	Lifetime	Inhalation	Study	of Talc:	18 mg/m	1 ³ (continued)

N 1 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0		7	-	-	8	8	8		8	8	8					_		_					8		8	
Number of Days on Study	8 4	8 6	9 6	3	2	3	8	9	3 5	1	1	2	8	5 0	5	5 7	6	6 2	6 2	6 2	6 2	6 3	6 3	6 3	3	
	2	_	2	2	1	1	-	_	_	-	1	_	-	2	2	1	1	_	1	_	_	_	_	_	2	
Carcass ID Number	5 7 1	8 7 1	3	5 3 1	6 2 1	6 4 1	5 7 1	7 7 1	1 5 1	9 0 1	9 1 1	0 5 1	5 8 1	6 4 1	3 1 1	6 5 1			6	2		8	5 4 1	9	8 6 1	Total Tissues Tumors
		_	_	_			_			_																
Alimentary System Esophagus	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Intestine large	·	+	•	+	+	À	+	+	+	+	+	+	+	+	À	+	+	÷	+	+	+	+	+	+	+	46
Intestine large, cecum	À	+	+	+	+	Ā	<u>.</u>	+	÷	÷	<u>.</u>	÷	+	÷	A	÷	+	+	+	+	+	+	+	+	+	43
Intestine large, colon	+	. ∔	·	+	<u>.</u>	A	<u>.</u>	+	<u>.</u>	+	<u>.</u>	+	<u>.</u>	<u>.</u>	A	+	+	<u>.</u>	+	+	+	+	+	+	+	45
Intestine large, rectum		·	į	÷	÷	A	÷	÷	м	+	÷	÷		÷	A	÷	÷	÷	÷	+	<u>.</u>	+	ì	+	<u>.</u>	41
Intestine small	÷	+		÷		Ā	+	÷	+	÷	÷	÷	+	÷		÷	÷		+	÷	÷	+			÷	48
Intestine small, duodenum		+		+	+	Â	+	+	+	+	+	+	+	+	+		+	+	+	+	+	+	+	+	+	47
Intestine small, ileum	À	i	i	·	i	Ä	+	i	i	i	À	+	i	ì		ż	Ė	÷	Ĺ	i	i		ì	·	i	38
Intestine small, jejunum		4	4	4	4	Â	+	+	+	+	+	+	+	+	+	+	+	1	<u>.</u>	_	-	4	4	4	<u>,</u>	46
Liver	1	4	4	4	i	-	ì	<u>.</u>	4	i	1	ï	<u>.</u>	_	1	+	1	Ι	ĭ	÷	4	i	4	Ĭ	1	50
Granulosa-theca tumor malignant, metastatic, ovary	•	т	7	•	•	т	_	•	•	т	т	T	•	T	•	·	•	_	•	7	T	•	1	•	_	1
Neoplastic nodule																X										1
Pancreas	+	+	+	+	+	#	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	49
Pharynx																										1
Squamous cell carcinoma																										1
Salivary glands	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Fibrosarcoma																Х										1
Stomach	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Stomach, forestomach	+	+	+	+	+	+	+	+	+	M	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	49
Stomach, glandular	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Cardiovascular System																										
Blood vessel										+																1
Heart	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Granulosa-theca tumor malignant, metastatic, ovary																										1
Endocrine System					_								_					-								
Adrenal gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	49
Adrenal gland, cortex	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	49
Granulosa-theca tumor malignant, metastatic, ovary																										1
Adrenal gland, medulla Granulosa-theca tumor malignant, metastatic, ovary	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	49 1
Pheochromocytoma malignant	X				X			x	X	x	x												x			ż
Pheochromocytoma benign	••		X		x		X	X	x	X	•			X						X			x		X	11
Bilateral, pheochromocytoma malignant							-								x		x				X				••	3
Bilateral, pheochromocytoma benign						x							x		-				X		,.	x		x		7
lslets, pancreatic	+	+	+	+	+	+	+	+	+	+	+	+		+	+	+	+	+	-	+	4	+		+		49
Adenoma	•	•	•	•	•	•	•	•	•	•	•	'	•	•	•	•	•	•	•	٠	•	•	•	•	•	1
							+																			47

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B-20 Talc, NTP TR 421

TABLE B2				
Individual Animal Tumor	Pathology of Female Rat	is in the Lifetime Inha	alation Study of Talc	18 mg/m³ (continued)

Individual Animal Tumor Pathology o	f Fen	ale	F	lat	s i	n t	he	L	fet	im	e I	nh	als	ıtic	n :	Stı	ıdy	0	f T	alc	= 1	18	mg	m	(continued)
	5	5		5	6	6	6	6	6	6	6	6	6	6	6	7	7	7	7	7	7	7	7	7	7
Number of Days on Study	3 6	5 8		9		3			1				8 4	3	7		0	1 6	7	2 4	9	4 0	6	7	
O	1	2	2	2	1	2 8	2 3		1 8				2 0				1 6		2 3					2 3	
Carcass ID Number	7	0	6	_		5	0	1	6	8	7	5	8	0	9	6	0	2	6	6	1	3	2	9	9
Endocrine System (continued)																									*
Pituitary gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Pars distalis, adenoma						X		X		X		X		X							X				
Pars distalis, carcinoma											X									X					
Thyroid gland	+	+	A	+	+	+	+	+	+	+	+		+	+	+	+	+	+	+	+	+	+	+	+	+
C-cell, carcinoma C-cell, carcinoma										v	х		X			·									
C-cell, carcinoma										_	^														
General Body System None																									
Genital System																									
Clitoral gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	M	+	M	+
Adenoma																									
Carcinoma																									•
Ovary	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Bilateral, granulosa-theca tumor																									
malignant									٠.							Х	+								
Uterus Polyp stromal	+	+	+	+	+	+	+	+	+	+	+	+ X	+	+	+	+	+	+	+	+	+	+	+	+	+
rotyp stromat	_																								
Hematopoietic System																									
Bone marrow	+	+	A	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Lymph node	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Lymph node, bronchial	+	+	+	+	+	+	+	+	+	+	+	M	+	+	M	+	+	+	+	M	+	+	+	+	+
Squamous cell carcinoma, metastatic,																٠.									
lung					4			1		,	ر					X +		,	,				B 4		
Lymph node, mandibular Lymph node, mediastinal	Ŧ		+	+	+	+	+	τ.	+	+	+	+	+	+	+	+	+	+	+	+	+	+	M	+	T
Carcinoma, metastatic, uncertain	7	-	7	7	7	_	7	*	7	_	_	_	+	*	7	7	7	+	7	*	_	_	~	_	7
primary site																									
Fibrosarcoma, metastatic, skin									x																
Granulosa-theca tumor malignant,																									
metastatic, ovary																X									
Lymph node, mesenteric	+	+	A	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Spiecn	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Thymus Schwannoma benign	+	+	+	M	M	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+

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TABLE B2				
Individual Animal Tumo	r Pathology of Female	Rats in the Lifetim	e Inhalation Study o	of Talc: 18 mg/m³ (continued)

Individual Animal Tumor Pathology	of Fer	na —-	le	R	ats ——	i	0 t	he	П	fet	im	e 1	ink	ıalı	atio	on —	Stı	udy	, o	r 1	alc	=] 	8	mg	/m	- (4	continued)
Number of Days on Study	7 8 4	8	3 9	9		2	2	2	2	3	4	4	4		5	8 5 4	5	6	6	6	6	6	6	6	8 6 3	6	
Carcass ID Number	2 5 7 1	7	,	3	5 3	6	6	1 5 7 1	7 7	1 5	9	9 1	0 5	2 5 8 1	6 4	2 3 1	6	5 8	6	6 6	8 2	3 2	3 8	2 5 4 1	5	6	Total Tissues Tumors
Endocrine System (continued) Pituitary gland Pars distalis, adenoma Pars distalis, carcinoma Thyroid gland C-cell, adenoma C-cell, carcinoma	+	. 4	- ·	+ X +	+	* * +	+ x +	+ *	+ *	* * +	* X +	+ X +	+ X +	+ X +	+ × +	* X +	+ x +	+	+ X +	+ *	+	+	+ X +	+ X +	+ *	+ X +	50 21 2 49 6 2
General Body System None																											
Genital System Clitoral gland Adenoma Carcinoma	+	. +		+	+	+	М	+	+	+ X	+	+	+	+	+	М	+	+	+	+	+	+ x	+	+	+	+	46 1 1
Ovary Bilateral, granulosa-theca tumor malignant Uterus Pohyp stromal	+ X	. +		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+ *	50 1 50 4
lematopoletic System Bone marrow Lymph node Lymph node, bronchial	+++++++++++++++++++++++++++++++++++++++	+++++++++++++++++++++++++++++++++++++++		+ +	+++	+ + +	+ + +	+ + +	+ + +	+ + +	+ + +	+ + +	+ + +	+ + +	+ + +	+ + +	+++	+ + +	+++	+ + +	+ + +	+ + +	+++	+++	+ + +	+ + +	49 50 47
Squamous cell carcinoma, metastatic, lung Lymph node, mandibular Lymph node, mediastinal Carcinoma, metastatic, uncertain	+	+	• •	+	+ +	+ +	+ +	+ +	+ +	+ +	++	++	+	+	+	M M	•	++	++	+ +	+ +	+ M	+	+	+	+ M	
primary site Fibrosarcoma, metastatic, skin Granulosa-theca tumor malignant, metastatic, ovary Lymph node, mezenteric Spiecen Thymus Schwannoma benign	+ + M	+		+ -	+ + +	+ + +	+ + +	+ + +	+ + +	+ + +	+ + +	+++	+ + +	+ + +	+ + +	M + +	+ + X	+ + +	M + +	+++	+++	+++	+ + +	+++	+ + +	+ + +	1 1 47 50 47 1

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B-22 Talc, NTP TR 421

TABLE B2		_
Individual Animal Tumor Pathology of Female	Rats in the Lifetime Inhalation	Study of Talc: 18 mg/m ³ (continued)

Tumaional Animai Inmoi I amonda of	, 1.01																-,						_			
Number of Days on Study	5 3 6	-	-	9	1	6 3 3	4	6 6 0	6		7	7	8	9	6 9 7	0	1	1	1	2	7 3 9	7 4 0	7 4 6	4	7 7 3	
Carcass ID Number	6	_	1	1 2	8	2 8 5 1	3	8	8	8	7	5	0 B			0 6	0	8 2	3 6	5 6	8 1	6	2	3	9	
Integumentary System Mammary gland Adenocarcinoma	+	. 4	. +	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
Adenoma Fibrosarcoma Fibrosarcoma Skin Keratoacanthoma Subcutaneous tissue, fibrosarcoma	+	· + X	· +	· +	+	+	+	+	+ X	+	+	x +	x +	+	+	+	+	+	+	x +	+	x +	+	x +	+	
Musculoskeletal System Bone	+	+		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	.+	
Nervous System Brain Carcinoma, metastatic, pituitary gland	+	. +		. +	+	+	+	+	+	+	*	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
Respiratory System Larynx Lung Alveolar/bronchiolar adenoma Alveolar/oronchiolar adenoma, multiple Alveolar/oronchiolar carcinoma Alveolar/oronchiolar carcinoma,	+	· +	· +	· +	+	1 +	++	I +	+ +	++	++	++	++	++	+	++	+++	+ + X	++	++	. + +	+ + X	++	++	++	
multiple Granulosa-theca tumor malignant, metastatic, ovary Squamous cell carcinoma Nose Trachea	+	+	· +	- + - +	+	++	++	+	++	++	++	++	++	+ +		X X + +	A +	+	++	++	++	++	++	++	++	
Special Senses System Eye Harderian gland Lacrimal gland										+	+	+		+					+	+		+			+	,, 1995 <u> </u>
Urinary System Kidney Urinary bladder	++	+	- A	· +	+	++	+	++	++	++	++	++	++	+ +	++	++	++	+	++	+	+	++	+	++	++	
Systemic Lesions Multiple organs Leukemia mononuclear	+ x	+	- *	• +	+ X	+ x	+	+ x		+ x		+	+ X	+	+		+ X	+	+	+	+ X		+		+ X	

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TABLE B2									
Individual Animal	Tumor Patholog	gy of Female	Rats in th	e Lifetime	Inhalation	Study o	f Tale: 18	mg/m³	(continued)

							_																			
Number of Days on Study	7 8 4	7 8 6	7 9 6	8 0 3	8 2 2	8 2 3	8 2 8	8 2 9	8 3 5	8 4 1	8 4 1	8 4 2	8 4 8	8 5 0	8 5 4	8 5 7	8 6 2	8 6 2	8 6 2	8 6 2	8 6 2	8 6 3	8 6 3	8 6 3	8 6 3	
Carcass ID Number	2 5 7 1	2 8 7 1	2 3 3	2 5 3 1	1 6 2 1	1 6 4 1	1 5 7 1	2 7 7 1	2 1 5	1 9 0 1	1 9 1	0	5 8	6	3	1 6 5 1	5	1 6 3 1	1 6 6 1	1 8 2 1	2 3 2 1	2 3 8 1	2 5 4 1	2 5 9 1	2 8 6 1	Total Tissues/ Tumors
Integumentary System Mammary gland Adenocarcinoma Adenoma Fibroadenoma Fibrosarcoma Skin Keratoacanthoma Subcutaneous tissue, fibrosarcoma	+	+	+	+	* x	+ X +	+ X +	+ x +	+ x +	+	* x x +	+	+ x +	+	+ x +	+	+	+	+ x +	+ x +	+ x +	+	+ x +	+	+	50 2 2 2 13 1 50 1
Musculoskeletal System Bone	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Nervous System Brain Carcinoma, metastatic, pituitary gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50 1
Respiratory System Larynx Lung Alveolar/bronchiolar adenoma Alveolar/bronchiolar adenoma, multiple Alveolar/bronchiolar carcinoma	+	+ + X	++	++	+	+ + X	+ + x x	+ + x	+ + X	+	++	+ + X	+ + x	++	+	++	+	++	+ + X	+ + x	+ + x	++	++	+	++	48 50 8 1 4
Alveolar/bronchiolar carcinoma, multiple Granulosa-theca tumor malignant, metastatic, ovary Squamous cell carcinoma Nose Trachea	A +	++	++	++	++	+	++	++	+ +	++	++	++	++	++	++	++	++	++	++	++	++	++	++	* + +	++	1 1 1 48 50
Special Senses System Eye Harderian gland Lacrimal gland	+		-	+							+	+	++	+		+						+			+	2 15 1
Urinary System Kidney Urinary bladder	+	++	++	++	++	++	++	++	+	++	++	+	+	++	++	++	++	++	+	++	++	++	++	++	++	49 50
Systemic Lesions Multiple organs Leukemia mononuclear	+	+ X	+	÷ x	+	+	+	+ X	+	+	÷ x	+	+	+	+	+	+ x	+	+	+	+	+	+ x	+	+ x	50 18

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B-24 Talc, NTP TR 421

TABLE B3
Statistical Analysis of Primary Neoplasms in Female Rats in the Lifetime Inhalation Study of Talc

	0 mg/m ³	6 mg/m ³	18 mg/m ³
Adrenal Medulia: Benign Pheochromocytoma			
Overall rates ²	13/48 (27%)	14/47 (30%)	18/49 (37%)
Adjusted rates ^b	61.3%	59.7%	82.5%
Terminal rates ^c	5/11 (45%)	5/13 (38%)	6/9 (67%)
First incidence (days)	678	705	697
Life table tests	P=0.135	P=0.529	P=0.183
Logistic regression tests ^d	P=0.185	P=0.541	P=0.225
Cochran-Armitage test ^d	P=0.180	024	. – 0
isher exact test ^d	. 4.254	P=0.474	P = 0.212
Adrenal Medulla: Malignant Pheochromocyto	na		
Overall rates	0/48 (0%)	1/47 (2%)	10/49 (20%)
Adjusted rates	0.0%	7.1%	56.9%
Terminal rates	0/11 (0%)	0/13 (0%)	3/9 (33%)
First incidence (days)	_e ` ´	849 ` ´	784
life table tests	P<0.001	P=0.531	P = 0.002
ogistic regression tests	P<0.001	P=0.509	P = 0.001
Cochran-Armitage test	P<0.001		
isher exact test		P=0.495	P<0.001
drenal Medulla: Benign or Malignant Pheoc	hromocytoma		
Overall rates	13/48 (27%)	14/47 (30%)	23/49 (47%)
Adjusted rates	61.3%	59.7%	95.2%
erminal rates	5/11 (45%)	5/13 (38%)	8/9 (89%)
irst incidence (days)	678	705	697
ile table tests	P=0.016	P=0.529	P=0.033
ogistic regression tests	P=0.014	P=0.541	P=0.024
Cochran-Armitage test	P=0.021		
isher exact test		P=0.474	P=0.034
iver: Neoplastic Nodule			
Overall rates	0/50 (0%)	3/48 (6%)	1/50 (2%)
Adjusted rates	0.0%	13.6%	10.0%
Terminal rates	0/11 (0%)	0/13 (0%)	0/9 (0%)
irst incidence (days)		724	857
ife table tests	P=0.550	P=0.114	P = 0.464
ogistic regression tests	P=0.561	P=0.117	P = 0.496
Cochran-Armitage test	P=0.556		
isher exact test		P=0.114	P=0.500
iver: Neoplastic Nodule or Hepatocellular Ca			
overall rates	0/50 (0%)	4/48 (8%)	1/50 (2%)
djusted rates	0.0%	20.2%	10.0%
crminal rates	0/11 (0%)	1/13 (8%)	0/9 (0%)
irst incidence (days)	_ D_0.686	724	857
ife table tests	P=0.575	P=0.066	P=0.464
ogistic regression tests	P=0.602	P = 0.060	P=0.496
Cochran-Armitage test	P=0.599	P-0.054	DO 500
BIICI CARCI ICAL		P = 0.054	P=0.500

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TABLE B3
Statistical Analysis of Primary Neoplasms in Female Rats in the Lifetime Inhalation Study of Talc (continued)

	0 mg/m ³	6 mg/m ³	18 mg/m ³	
Lung: Alveolar/bronchiolar Adenoma				
Overall rates	1/50 (2%)	0/48 (0%)	9/50 (18%)	
Adjusted rates	4.5%	0.0%	40.8%	
Terminal rates	0/11 (0%)	0/13 (0%)	1/9 (11%)	
First incidence (days)	805	-	716	
Life table tests	P<0.001	P=0.529N	P=0.015	
Logistic regression tests	P<0.001	P=0.503N	P=0.010	
Cochran-Armitage test	P<0.001	1 3233.		
Fisher exact test	• •	P=0.510N	P = 0.008	
Lung: Alveolar/bronchiolar Carcinoma				
Overall rates	0/50 (0%)	0/48 (0%)	5/50 (10%)	
Adjusted rates	0.0%	0.0%	41.7%	
Terminal rates	0/11 (0%)	0/13 (0%)	3/9 (33%)	
First incidence (days)	<u>-</u>	_ ' '	82 8 `	
Life table tests	P=0.002	_t	P=0.027	
Logistic regression tests	P=0.003	-	P=0.028	
Cochran-Armitage test	P=0.004			
Fisher exact test		-	P=0.028	
Lung: Alveolar/bronchiolar Adenoma or Carcino				
Overall rates	1/50 (2%)	0/48 (0%)	13/50 (26%)	
Adjusted rates •	4.5%	0.0%	65.8%	
Terminal rates	0/11 (0%)	0/13 (0%)	4/9 (44%)	
First incidence (days)	805	-	716	
Life table tests	P<0.001	P=0.529N	P=0.001	
Logistic regression tests	P<0.001	P=0.503N	P<0.001	
Cochran-Armitage test	P<0.001			
Fisher exact test		P=0.510N	P<0.001	
Mammary Gland: Fibroadenoma				
Overall rates	11/50 (22%)	10/49 (20%)	13/50 (26%)	
Adjusted rates Ferminal rates	47.6%	41.4%	64.0%	
	2/11 (18%)	3/13 (23%)	4/9 (44%)	
Tirst incidence (days) Life table tests	634 P=0.304	482 B=0.480N	678 D=0.204	
Logistic regression tests	P=0.363	P=0.489N P=0.508N	P=0.394 P=0.428	
Cochran-Armitage test	P=0.343	1=0206N	r=0.428	
Fisher exact test	r=0.543	P=0.521N	P=0.408	
Mammary Gland: Fibroma, Fibroadenoma, or A	denoma			
Overall rates	13/50 (26%)	13/49 (27%)	15/50 (30%)	
Adjusted rates	54.7%	59.0%	68.6%	
Terminal rates	3/11 (27%)	6/13 (46%)	4/9 (44%)	
First incidence (days)	634	482	678	
ife table tests	P=0.314	P=0.544N	P=0.404	
ogistic regression tests	P=0.394	P=0.585	P=0.434	
Cochran-Armitage test	P=0.371			
-		P=0.567		

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B-26 Talc, NTP TR 421

TABLE B3
Statistical Analysis of Primary Neoplasms in Female Rats in the Lifetime Inhalation Study of Talc (continued)

	0 mg/m ³	6 mg/m ³	18 mg/m ³
Mammary Gland: Fibroma, Fibroadenoma,	Adenoma, or Adenocarcinoma	****	
Overall rates	15/50 (30%)	13/49 (27%)	16/50 (32%)
Adjusted rates	56.6% `	59.0%	70.1%
Terminal rates	3/11 (27%)	6/13 (46%)	4/9 (44%)
First incidence (days)	370	482	678
Life table tests	P=0.378	P=0.386N	P=0.494
Ogistic regression tests	P=0.457	P=0.425N	P=0.531
Cochran-Armitage test	P=0.430		
Fisher exact test		P=0.437N	P=0.500
Pitultary Cland (Pars Distalis): Adenoma			
Overall rates	19/50 (38%)	18/47 (38%)	21/50 (42%)
Adjusted rates	62.1%	60.5% `	78.3%`´
Ferminal rates	3/11 (27%)	3/13 (23%)	4/9 (44%)
irst incidence (days)	568 `	697 ` ´	633 `
ife table tests	P=0.360	P=0.512N	P=0.425
ogistic regression tests	P=0.409	P=0.557N	P=0.457
Cochran-Armitage test	P=0.380		
isher exact test		P=0.571	P=0.419
rituitary Gland (Pars Distalis): Carcinoma			
Overall rates	3/50 (6%)	3/47 (6%)	2/50 (4%)
djusted rates	17.1%	12.2%	5.6%
erminal rates	1/11 (9%)	1/13 (8%)	0/9 (0%)
irst incidence (days)	69 6	566	676
ife table tests	. P=0.438N	P=0.636N	P=0.506N
ogistic regression tests	P=0.427N	P=0.634	P=0.497N
Cochran-Armitage test	P=0.418N		
isher exact test		P=0.631	P=0.500N
ituitary Gland (Pars Distalis): Adenoma o			
verall rates	22/50 (44%)	21/47 (45%)	23/50 (46%)
djusted rates	69.8%	66.2%	79.5%
erminal rates	4/11 (36%)	4/13 (31%)	4/9 (44%)
irst incidence (days)	568	566	633
ife table tests	P=0.429	P=0.502N	P=0.488
ogistic regression tests	P=0.506	P=0.570N	P=0.545
ochran-Armitage test isher exact test	P=0.471	P=0.554	P=0.500
hymnid Cland (C noll): Adamous		· · · · · · · · · · · · · · · · · · ·	
hyroid Gland (C-cell): Adenoma	E (ED / 1077)	DUS (00)	(110 (100)
	5/50 (10%)	0/47 (0%)	6/49 (12%)
djusted rates	33.5% 201 (19%)	0.0%	34.0%
erminal rates	2/11 (18%)	0/13 (0%)	2/9 (22%)
irst incidence (days)	805 D-0.000	- D 0.0001	678
ife table tests	P=0.253	P=0.030N	P=0.467
ogistic regression tests	P=0.283	P = 0.029N	P=0.505
ochran-Armitage test isher exact test	P=0.276	B-0.022N	D-0404
INICE CYSCI ICN	•	P=0.033N	P=0.486

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TABLE B3
Statistical Analysis of Primary Neoplasms in Female Rats in the Lifetime Inhalation Study of Talc (continued)

	0 mg/m ³	6 mg/m ³	18 mg/m ³
Thyroid Gland (C-cell): Carcinoma			
Overall rates	3/50 (6%)	2/47 (4%)	2/49 (4%)
Adjusted rates	11.1%	12.2%	4.9%
Terminal rates	0/11 (0%)	0/13 (0%)	0/9 (0%)
First incidence (days)	677	818	675
Life table tests	P=0.430N	P=0.507N	P=0.493N
Logistic regression tests	P=0.462N	P=0.516N	P=0.533N
Cochran-Armitage test	P=0.463N	1 – 021011	. – 02251.
Fisher exact test		P=0.530N	P=0.510N
Thyroid Gland (C-cell): Adenoma or Carcinoma			
Overall rates	8/50 (16%)	2/47 (4%)	8/49 (16%)
Adjusted rates	40.9% ´	12.2%	37.2%
Terminal rates	. 2/11 (18%)	0/13 (0%)	2/9 (22%)
First incidence (days)	677 ` ´	818 ` .	675 `
Life table tests	P=0.418	P=0.051N	P=0.579
Logistic regression tests	P=0.435	P=0.048N	P=0.599N
Cochran-Armitage test	P=0.414		
Fisher exact test		P=0.056N	P=0.590
Uterus: Stromal Polyp			
Overall rates	5/50 (10%)	7/49 (14%)	4/50 (8%)
Adjusted rates	22.3%	34.4%	19.5%
Terminal rates	1/11 (9%)	3/13 (23%)	1/9 (11%)
First incidence (days)	398	678	678
Life table tests	P=0.439N	P=0.400	P=0.532N
Logistic regression tests	P=0.376N	P = 0.372	P=0.505N
Cochran-Armitage test	P=0.386N		
Fisher exact test		P=0.365	P=0.500N
Uterus: Stromal Polyp or Stromal Sarcoma			
Overall rates	5/50 (10%)	8/49 (16%)	4/50 (8%)
Adjusted rates	22.3%	35.8%	19.5%
Terminal rates	1/11 (9%)	3/13 (23%)	1/9 (11%)
First incidence (days) Life table tests	398 B-0 412N	557	678
	P=0.412N	P=0.298	P=0.532N
Logistic regression tests Cochran-Armitage test	P=0.360N P=0.363N	P=0.265	P=0.505N
Fisher exact test	r =u.303N	P=0.264	P=0.500N
All Organs: Mononuclear Cell Leukemia			
Overall rates	13/50 (26%)	20/49 (41%)	18/50 (36%)
Adjusted rates	45.7%	73.3%	60.1%
Ferminal rates	1/11 (9%)	8/13 (62%)	3/9 (33%)
First incidence (days)	390	526	536
ife table tests	P=0.234	P=0.164	P=0.232
ogistic regression tests	P=0.226	P=0.084	P=0.152
Cochran-Armitage test	P=0.250		
Fisher exact test		P=0.088	P=0.194

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Talc, NTP TR 421

Table B3
Statistical Analysis of Primary Neoplasms in Female Rats in the Lifetime Inhalation Study of Talc (continued)

	0 mg/m ³	6 mg/m ³	18 mg/m ³	
All Organs: Malignant Lymphoma				
Overall rates	0/50 (0%)	3/49 (6%)	0/50 (0%)	
Adjusted rates	0.0%	10.3%	0.0%	
Terminal rates	0/11 (0%)	0/13 (0%)	0/9 (0%)	
First incidence (days)	- ` ´	724	-	
Life table tests	P=0.525N	P=0.124	-	
Logistic regression tests	P=0.497N	P=0.118	-	
Cochran-Armitage test	P=0.499N			
Fisher exact test		P=0.117	-	
All Organs: Benign Tumors				٠
Overall rates	38/50 (76%)	35/49 (71%)	39/50 (78%)	
Adjusted rates	97.2%	96.9%	97.4%	
Terminal rates	10/11 (91%)	. 12/13 (92%)	8/9 (89%)	
First incidence (days)	398	482	558	
Life table tests	P=0.338	P=0.350N	P=0.440	
Logistic regression tests	P=0.544	P=0.312N	P=0.562N	
Cochran-Armitage test	P=0.415			
Fisher exact test		P=0.387N	P=0.500	
All Organs: Malignant Tumors				
Overall rates	23/50 (46%)	31/49 (63%)	35/50 (70%)	
Adjusted rates	69.3%	85.8%	90.5%	
Terminal rates	4/11 (36%)	9/13 (69%)	6/9 (67%)	
First incidence (days)	370	526	536	
Life table tests	P=0.054	P=0.189	P=0.061	
Logistic regression tests	P=0.013	P=0.056	P = 0.010	
Cochran-Armitage test	P=0.016			
Fisher exact test		P=0.064	P=0.013	
All Organs: Benign or Malignant Tumors				
Overall rates	44/50 (88%)	47/49 (96%)	49/50 (98%)	
Adjusted rates	97.6%	97.9%	100.0%	
Terminal rates	10/11 (91%)	12/13 (92%)	9/9 (100%)	
First incidence (days)	3 7 0	482	536	
Life table tests	P=0.248	P=0.447	P = 0.279	
Logistic regression tests	P=0.053	P=0.145	P = 0.060	
Cochran-Armitage test	P=0.049			
Fisher exact test		P=0.141	P=0.056	

Number of tumor-bearing animals/number of animals examined. Denominator is number of animals examined microscopically for adrenal gland, bone marrow, brain, clitoral gland, epididymis, gallbladder (mouse), heart, kidney, larynx, liver, lung, nose, ovary, pancreas, parathyroid gland, pituitary gland, preputial gland, prostate gland, salivary gland, spleen, testes, thyroid gland, and urinary bladder; for other tissues, denominator is number of animals necropsied.

B-28

Value of statistic cannot be computed.

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Kaplan-Meier estimated tumor incidence at the end of the study after adjustment for intercurrent mortality

^c Observed incidence at terminal kill

Beneath the control incidence are the P values associated with the trend test. Beneath the dosed group incidence are the P values corresponding to pairwise comparisons between the controls and that dosed group. The life table analysis regards tumors in animals dying prior to terminal kill as being (directly or indirectly) the cause of death. The logistic regression tests regard these lesions as nonfatal. The Cochran-Armitage and Fisher exact tests compare directly the overall incidence rates. For all tests, a negative trend or a lower incidence in a dose group is indicated by N.

Not applicable; no tumors in animal group